5 510(k) Summary

K092018

5.1 510(k) owner

SEP 18 2009

IBA Dosimetry GmbH
Bahnhofstrasse 5
90592 Schwarzenbruck
Germany

Tel: +49 9128 607 0
Fax: +49 9128 607 10

5.2 Contact Person

Martin Arold

5.3 Preparation date

2009-06-09

5.4 Trade Name

OminPro Incline

5.5 Common name

Radiation therapy dose calculation QA tool.

5.6 Classification Name

Accelerator, linear, medical

5.7 Predicate Devices

Omni-Pro Accept: K011763

5.8 Device Description

The Omni-Pro Incline software is a workspace tool managing both the measurements and the analysis of depth dose distributions of particles with a range up to 33 cm Water Equivalent Thickness (WET). The software is delivered with a dedicated system of multi layer of ionization chambers and with a dedicated electrometer based on the Tera chip technology. Single Bragg peaks as well as modulated distributions can be measured and analyzed with high spatial and temporal resolution (in the order of 2mm WET) with typical sampling time down to 10ms. The data format will be directly compatible with the one of the IBA Dosimetry conventional formats and at least easily exchangeable. The system is suitable for both active and passive delivery

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

IBA Dosimetry GmbH
% Mr. Chuck Lindley
President
IBA Dosimetry America
3150 Stage Post Dr., Suite 110
BARTLETT TN 38133

Re: K092018
Trade/Device Name: OmniPro Incline
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 6, 2009
Received: July 6, 2009

Dear Mr. Lindley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): - K092018

Device Name: OmniPro Incline

Indications for Use:

The OmniPro Incline is a QA beam measuring system intended to be used for the verification of dose distribution in radio therapy. The system is intended to measure proton, photon and electron beams.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092018